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**Please find below and/or attached an Office communication concerning this application or proceeding.**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/605,125  
Filing Date: 10 September, 2004  
Appellant(s): Walsh et al.

Jerome R. Drouillard  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 5 February, 2010 appealing from the Office action mailed 27 October, 2009.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the Appeal Brief.

**(2) Related Appeals and Interferences**

There are no other known appeals or interferences which will directly affect or be directly affected by or have bearing on the Board's decision in the pending appeal

**(3) Status of Claims**

The statement of the status of claims contained in the Appeal Brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the Appeal Brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the Appeal Brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal contained in the Appeal Brief is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appeal Brief is correct.

**(8) Evidence relied Upon**

Atlas Medical, Inc. Atlas Lab Works ([www.atlasdev.com](http://www.atlasdev.com)) web pages dated 2 August, 2002

US 5,692,220 A	Diamond et al.	11-1997
US 5,737,539 A	Edelson et al.	04-1998
US 5,819,242 A	Matsuoka et al.	10-1998
US 5,823,948 A	Ross et al.	10-1998
US 2002/0071540 A1	Dworkin, David S.	06-2002
US 2002/0099586 A1	Bladen et al.	07-2002
US 2003/0069759 A1	Smith, Kevin L.	04-2003

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**Claims 1 – 21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1, 14 and 16 claim an “imbedded consultant” (i.e. potentially, a human being).**

On April 7, 1987, then Assistant Secretary and Commissioner of Patents and Trademarks, Donald J. Quigg, set forth PTO policy on this issue in the form of a notice entitled "Animals - Patentability". The notice affirmed that the "Patent and Trademark Office now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101" and relied on the now famous Supreme Court decision *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980).

However, Commissioner Quigg's notice also went on to affirm the long-standing PTO principle and practice that products found in nature will not be considered to be patentable subject matter under 35 U.S.C. 101. Specifically, the Commissioner stated that a "claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101" since the grant of a limited, but exclusive property right in a human being is prohibited by the Constitution (presumably the 13th Amendment). The language "including within its scope a human being" is the important language here.

Accordingly, where a claim is directed to apparatus "attached to" the human body or any part thereof it may be appropriate to make a rejection under 35 U.S.C. 101 with an explanation that, because the claim positively recites a part of the human body, it is

directed to nonstatutory subject matter. Beyond the statute itself, proper authority for such a rejection is Commissioner Quigg's notice which was published at 1077 OG 24 (April 21, 1987).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 18 and 22 – 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The term "*desirable*" in claim 18 is a relative term which renders the claim indefinite. The term "*desirable*" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "*remarkable*" in claim 22 is a relative term which renders the claim indefinite. The term "*remarkable*" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1, 3, 9, 11, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002 and in further view of Bladen et al. (US PG PUB 2002/0099586 A1).**

**CLAIM 1**

Atlas LabWorks as shown discloses a laboratory order entry and results reporting system with the following limitations:

- *an order entry subsystem for submitting orders for at least one diagnostic test;*
- *a laboratory for receiving said orders and for managing patients to fill said orders, thereby generating test results;*

- *a data storage subsystem for receiving and retaining test results from said laboratory;*
- *a triage subsystem for comparing test results downloaded from said data storage subsystem with a predetermined reference range specific to such results;*
- *triage subsystem setting an abnormal results flag in the event that the test results are outside of said reference range;*
- *a reporting-consulting subsystem for receiving the results of said comparison from said triage subsystem;*
- *reporting-consulting subsystem transmitting the processed test results, comprising at least the results of said comparison, to the person requesting said at least one diagnostic test.*
- *the reporting-consulting subsystem further transmitting results bearing an abnormal results flag to an embedded consultant; (see at least Atlas LabWorks web pages).*

Atlas LabWorks as shown discloses the limitations above. Atlas LabWorks does not disclose the following limitations, however, Bladen does;

- *a consultant; (see at least Bladen paragraph 0005 and 0243);*
- *reporting-consulting subsystem providing at least one template for selection by said consultant to generate a consultative report concerning the test results; (see at least Bladen paragraph 0005 and 0242 to 0244).*

Bladen discloses a risk assessment system which includes consultant selected templates.

Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the laboratory test management system of Atlas LabWorks so as to



have included consultant selected templates, in accordance with the teaching of Bladen, in order to allow for effective reporting of the consultants findings for the laboratory results, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

**CLAIMS 3, 9, 11 and 13**

Atlas LabWorks/Bladen as shown discloses the limitations above relative to Claim 1.

Additionally, Atlas LabWorks discloses the following limitations:

- *template provided by said reporting-consulting subsystem further comprises at least one data source for providing data for generating said consultative report, with said data source providing said data as a function of at least the value of said test results;*
- *reference range is determined as a function of at least one prior recorded test result for the patient being tested;*
- *an alert subsystem for establishing a time-based test sequence, with said reporting-consulting subsystem contacting said clinician in the event that patient test results are not entered into said data storage subsystem according to a specified time interval, with said alert subsystem also having the capability of causing the clinician to be contacted in the event that said test results indicate that said patient requires immediate intervention;*
- *interpretative data comprise at least one of: patient-specific archival data, generic tabular data, generic graphical data, and patient-specific graphical data; (see at least Atlas LabWorks web pages).*

## **CLAIMS 14 and 15**

Atlas LabWorks as shown discloses a laboratory order entry and results reporting system with the following limitations:

- *an Internet based order entry subsystem, accessible by clinicians, for submitting orders for diagnostic tests to a laboratory;*
- *a data storage subsystem for receiving and retaining both contemporary and archival laboratory test results;*
- *a triage subsystem for downloading said test results from said data storage subsystem;*
- *triage subsystem comparing said test results with predetermined reference range values;*
- *triage subsystem causing the test results to be transmitted over a computer network to both the requesting clinician and to a reporting-consulting subsystem in the event that the test results are outside said reference range values;*
- *a reporting-consulting subsystem for receiving said test results lying outside of said reference range;*
- *report being based upon said test results;*
- *template comprising at least one data source for providing data for generating said report;*
- *data source providing said data as a function of at least the value of said test results;*
- *triage subsystem causes archival test results contained within said data storage subsystem to be transferred to said clinician at the same time contemporary test results are transferred to the clinician; (see at least Atlas LabWorks web pages).*

Atlas LabWorks as shown discloses the limitations above. Atlas LabWorks does not disclose the following limitations, however, Bladen does:

- *providing at least one template, selectable by an embedded consulting physician using a networked terminal; (see at least Bladen paragraph 0005 and 0242 to 0244);*
- *said consulting physician generating a consultative report using said template and said networked terminal; (see at least Bladen paragraph 0005 and 0242 to 0244).*

Bladen discloses a risk assessment system which includes consultant selected templates.

Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the laboratory test management system of Atlas LabWorks so as to have included consultant selected templates, in accordance with the teaching of Bladen, in order to allow for effective reporting of the consultants findings for the laboratory results, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

**Claims 2, 4, 5, 12, 22, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002 and in further view of Bladen et al. (US PG PUB 2002/0099586 A1) and in further view of Edelson et al. (US 5,737,539 A).**

**CLAIMS 2, 4, 5 and 12**

Atlas LabWorks/Bladen as shown discloses the limitations above relative to Claim 1. Atlas LabWorks/Bladen does not disclose the following limitations, however, Edelson does:

- *at least one data source for providing interpretive data for generating said consultative report; (see at least Edelson column 5 line 40 – 65 and column 47 line 1 – 7; line 15 - 18 and line 27 - 36);*
- *at least one computer-linked source of additional information for use by said consultant for generating said consultative report; (see at least Edelson column 5 line 40 – 65 and column 47 line 1 – 7; line 15 - 18 and line 27 - 36);*
- *computer-linked source of additional information comprises an Internet-based source; (see at least Edelson column 5 line 40 – 65 and column 47 line 1 – 7; line 15 - 18 and line 27 - 36);*
- *template incorporates interpretative data for use by the embedded consultant in the event that the test results require additional analysis; (see at least Edelson column 5 line 40 – 65 and column 47 line 1 – 7; line 15 - 18 and line 27 - 36).*

Edelson discloses a prescription creation system which includes providing interpretive data over the Internet. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the laboratory test management system of Atlas

LabWorks/Bladen so as to have included providing interpretive data over the Internet, in accordance with the teaching of Edelson, in order to allow for effective decision making, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

## **CLAIM 22**

Atlas LabWorks as shown discloses a laboratory order entry and results reporting system with the following limitations:

- *an Internet based order entry subsystem for use by a clinician to submit orders for diagnostic tests;*
- *a data storage subsystem for receiving and retaining test results from a clinical laboratory;*
- *a triage subsystem for comparing said test results with predetermined range values;*
- *triage subsystem causing the test results to be transmitted by a reporting- consulting subsystem directly to the test requestor via the Internet;*
- *triage subsystem causing the test results to be transmitted to a reporting-consulting subsystem in the event that the test results are remarkable in view of said predetermined range values; (see at least Atlas LabWorks web pages).*

Atlas LabWorks as shown discloses the limitations above. Atlas LabWorks does not disclose the following limitations, however, Bladen does:

- *with said reporting-consulting subsystem receiving said remarkable test results and providing at least one template for selection by a consultant to generate a consultative report concerning the test results; (see at least Bladen paragraph 0005 and 0242 to 0244).*

Bladen discloses a risk assessment system which includes consultant selected templates.

Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the laboratory test management system of Atlas LabWorks so as to have included consultant selected templates, in accordance with the teaching of Bladen, in order to allow for effective reporting of the consultants findings for the laboratory results, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

Atlas LabWorks/Bladen as shown discloses the limitations above. Atlas LabWorks/Bladen does not disclose the following limitations, however, Edelson does:

- *with said template comprising at least one Internet link to an additional source of diagnostic information; (see at lease Edelson column 5 line 40 – 65 and column 47 line 1 – 7; line 15 - 18 and line 27 - 36).*

Edelson discloses a prescription creation system which includes providing interpretive data over the Internet. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the laboratory test management system of Atlas LabWorks/Bladen so as to have included providing interpretive data over the Internet, in

accordance with the teaching of Edelson, in order to allow for effective decision making, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

#### **CLAIMS 26 and 27**

Atlas LabWorks/Bladen/Edelson as shown discloses the limitations above relative to Claim 22.

Additionally, Atlas LabWorks discloses the following limitations:

- *predetermined range values comprise a reference range selected as a function of at least one prior test result of the patient being tested;*
- *consultative report comprises at least one URL for use by the clinician receiving the consultative report; (see at least Atlas LabWorks web pages).*

**Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Atlas Medical, Inc.**

**Atlas LabWorks web site dated 2 August, 2002 and in further view of Bladen et al.**

**(US PG PUB 2002/0099586 A1) and in further view of Edelson et al. (US 5,737,539 A) and in further view of Ross et al. (US 5,823,948 A).**

#### **CLAIM 28**

Atlas LabWorks/Bladen/Edelson as shown discloses the limitations above relative to Claim 22.

Atlas LabWorks/Bladen/Edelson does not specifically disclose the following limitation, however, Ross does:

- *a billing routine for invoicing said patient's insurer by means of an invoice bearing an AMA CPT code; (see at least Ross column 1 line 50 – 61).*

Ross discloses a medical records system which includes billing for care provided. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the laboratory test management system of Atlas LabWorks/Bladen/Smith so as to have included billing for care provided, in accordance with the teaching of Ross, in order to allow for proper medical claim billing, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

**Claims 6, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002 and in further view of Bladen et al. (US PG PUB 2002/0099586 A1) and in further view of Dworkin (US PG PUB 2002/0071540 A1).**

**CLAIMS 6, 7, and 8**

Atlas LabWorks/Bladen as shown discloses the limitations above relative to Claim 1.

Additionally, Atlas LabWorks/Bladen does not disclose the following limitations, however, Dworkin does:

- *a conferencing subsystem for scheduling a conference between the person submitting the test request and the embedded consultant who generated said consultative report; (see at least Dworkin paragraphs 0002 to 0007);*
- *a conferencing subsystem for scheduling a computer net meeting between the test requester and the embedded consultant who generated said consultative report; (see at least Dworkin paragraphs 0002 to 0007);*



- *a conferencing subsystem for scheduling a net meeting between the test requestor, the embedded consultant who generated said consultative report, and at least one additional consultant; (see at least Dworkin paragraphs 0002 to 0007).*

Dworkin discloses a conferencing system which includes scheduling conferences over the Internet among a plurality of participants. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the laboratory test management system of Atlas LabWorks/Bladen so as to have included scheduling conferences over the Internet among a plurality of participants, in accordance with the teaching of Dworkin, in order to allow for effective communication, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

**Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002 and in further view of Bladen et al. (US PG PUB 2002/0099586 A1) and in further view of Matsuoka et al. (US 5,819,242 A).**

#### **CLAIM 10**

Atlas LabWorks/Bladen as shown discloses the limitations above relative to Claim 1.

Additionally, Atlas LabWorks/Bladen does not disclose the following limitations, however, Matsuoka does:

- *uploading previous test results for a plurality of patients and a subroutine for predicting future test results based at least in part upon said stored test results; (see at least Matsuoka column 19 line 28 – 41).*

Matsuoka discloses a neural network system which includes predicting future outcomes base on previous test results. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the laboratory test management system of Atlas LabWorks/Bladen so as to have included predicting future outcomes base on previous test results, in accordance with the teaching of Matsuoka, in order to allow for effective diagnosis of diseases, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

**Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002 and in further view of Bladen et al. (US PG PUB 2002/0099586 A1) and in further view of Smith (US PG PUB 2003/0069759 A1).**

#### **CLAIM 16**

Atlas LabWorks as shown discloses a laboratory order entry and results reporting system with the following limitations:

- *submitting an order to a laboratory for a diagnostic test by means of a networked terminal device;*
- *managing a patient to fill said test order, thereby generating test results;*

- *loading said test results into a data storage subsystem;*
- *comparing said test results contained within said data storage subsystem with predetermined reference range values;*
- *causing the test results to be transmitted directly to the test requestor, using a networked terminal device, in the event that the test results are within said reference range;*
- *causing the test results to be transmitted by a networked terminal device to a consulting physician via a consultative reporting-consulting subsystem in the event that the test results are outside said reference range;*
- *receiving said test results lying outside of said reference range in a reporting-consulting subsystem; (see at least Atlas LabWorks web pages).*

Atlas LabWorks as shown discloses the limitations above. Atlas LabWorks does not disclose the following limitations, however, Bladen does:

- *using said reporting-consulting subsystem to provide at least one selectable report template; (see at least Bladen paragraph 0005 and 0242 to 0244);*
- *using said report template and said consulting physician to generate a consultative report based at least in part upon the test results; (see at least Bladen paragraph 0005 and 0242 to 0244).*

Bladen discloses a risk assessment system which includes consultant selected templates.

Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the laboratory test management system of Atlas LabWorks so as to have included consultant selected templates, in accordance with the teaching of Bladen, in order

to allow for effective reporting of the consultants findings for the laboratory results, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

The combination of Atlas/Bladen discloses the limitations shown above. Atlas/Bladen does not specifically disclose the following limitations, however, Smith does:

- *communicating said consultative report, bearing an electronic signature, to the test requester by means of a networked terminal device; (see at least Smith paragraph 0173).*

Smith discloses a healthcare management system which electronic signatures. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the laboratory test management system of Atlas LabWorks/Bladen so as to have included electronic signatures, in accordance with the teaching of Bladen, in order to allow for proper documentation of laboratory result findings, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

## **CLAIM 18**

Atlas LabWorks as shown discloses the limitations above relative to Claim 16. Additionally, Atlas LabWorks discloses the following limitations:

- *requesting and performing additional reflexive tests in the event that said test results indicate that such testing is desirable, with the results of said reflexive tests being communicated to said test requester by means of a networked terminal device; (see at least Atlas LabWorks web pages).*

**Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002 and in further view of Bladen et al. (US PG PUB 2002/0099586 A1) and in further view of Smith (US PG PUB 2003/0069759 A1) and in further view of Edelson et al. (US 5,737,539 A).**

**CLAIM 17**

The combination of Atlas/Bladen/Smith as shown discloses the limitations above relative to Claim 16. Atlas/Bladen/Smith does not specifically disclose the following limitations, however, Edelson does:

- *report template incorporates at least one importable additional data source for providing test result driven data for generating said consultative report; ; (see at least Edelson column 5 line 40 – 65 and column 47 line 1 – 7; line 15 - 18 and line 27 - 36).*

Edelson discloses a prescription creation system which includes providing additional data over the Internet. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the laboratory test management system of Atlas LabWorks/Bladen/Smith so as to have included providing additional data over the Internet, in accordance with the teaching of Edelson, in order to allow for effective decision making, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

**Claim 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002 and in further view of Bladen et al. (US PG PUB 2002/0099586 A1) and in further view of Smith (US PG PUB 2003/0069759 A1) and in further view of Dworkin (US PG PUB 2002/0071540 A1).**

**CLAIMS 19 and 20**

The combination of Atlas/Bladen/Smith as shown discloses the limitations above relative to Claim 16. Atlas/Bladen/Smith does not specifically disclose the following limitations, however, Dworkin does:

- *inking the test requestor to a conferencing system by means of a networked terminal device, for scheduling a conference with the consultant who generated said consultative report; (see at least Dworkin paragraphs 0002 to 0007).*
- *linking the test requestor to a conferencing system by means of a networked terminal device, for scheduling a net meeting with at least the consultant who generated said consultative report; (see at least Dworkin paragraphs 0002 to 0007).*

Dworkin discloses a conferencing system which includes scheduling conferences over the Internet among a plurality of participants. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the laboratory test management system of Atlas LabWorks/Bladen so as to have included scheduling conferences over the Internet among a plurality of participants, in accordance with the teaching of Dworkin, in order to allow for effective communication, since so doing could be performed readily and

easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

**Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002 and in further view of Bladen et al. (US PG PUB 2002/0099586 A1) and in further view of Smith (US PG PUB 2003/0069759 A1) and in further view of Ross et al. (US 5,823,948 A).**

**CLAIM 21**

The combination of Atlas/Bladen/Smith as shown discloses the limitations above relative to Claim 16. Atlas/Bladen/Smith does not specifically disclose the following limitations, however, Ross does:

- *billing the patient's insurer for the time expended by the consulting physician to analyze said test results and to draft said consultative report; (see at least Ross column 1 line 50 – 61).*

Ross discloses a medical records system which includes billing for care provided. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the laboratory test management system of Atlas LabWorks/Bladen/Smith so as to have included billing for care provided, in accordance with the teaching of Ross, in order to allow for proper medical claim billing, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

**Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002 and in further view of Bladen et al. (US PG PUB 2002/0099586 A1) and in further view of Edelson et al. (US 5,737,539 A) and in further view of Smith (US PG PUB 2003/0069759 A1).**

**CLAIMS 23-25**

The combination of Atlas/Bladen/Edelson as shown discloses the limitations above relative to Claim 22. Atlas/Bladen/Edelson does not specifically disclose the following limitations, however, Smith does:

- *provides for the affixing of said consultant's electronic signature to said consultative report and for sending the consultative report to the requesting clinician via the Internet;* (see at least Smith paragraph 0173);
- *electronic signature is a digital signature;* (see at least Smith paragraph 0173).

Smith discloses a healthcare management system which electronic signatures. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the laboratory test management system of Atlas LabWorks/Bladen/Edelson so as to have included electronic signatures, in accordance with the teaching of Bladen, in order to allow for proper documentation of laboratory result findings, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.



With regards to the limitation:

- *electronic signature is a digital signature meeting the requirements of the Health Insurance Portability and Accountability Act ("HIPAA").*

It would be obvious to one of ordinary skill in the art at the time the invention was made to modify the laboratory test management system of Atlas/Bladen/Edelson/Smith to provide that the electronic signature meets HIPAA requirements in order to allow for proper documentation of laboratory result findings, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

#### **(10) Response to Arguments**

**In the Appeal Brief filed 5 February, 2010 Appellant makes the following arguments:**

##### **Argument 1**

Appellant argues that the 35 U.S.C. 101 rejection of claims 1 – 21 is wholly without merit because the claimed invention is not “attached to a human body”, rather that the embedded consultant is an integral component of the testing and reporting process.

## **Argument 2**

Appellant argues the 35 U.S.C. 112 second paragraph rejection of Claims 18 and 22 – 28, is improper because the terms “desirable” and “remarkable” are clear when teamed with the usage in appellant’s specification. Appellant argues that the specification provides an explicit definition for the terms “remarkable” and “desirable”.

## **Argument 3**

Appellant argues that Bladen does not disclose a consultant or a reporting consulting subsystem, and that Bladen does not disclose the use of a human consultant working with a template provided by a reporting consulting subsystem to produce a consultative report.

## **Argument 4**

Appellant argues that neither Atlas nor Bladen discloses: a template having a data source for generating a consultative report; reference ranges determined as a function of prior test results; an alert subsystem; or interpretive data comprising patient specific data.

## **Argument 5**

Appellant argues that Ross does not disclose an invoice provided with CPT coding or any specific billing process.

**Argument 6**

Appellant argues that Dworkin, Matsouka, Smith and Edelson do not correct the deficiencies of Atlas/Bladen with respect to disclosing the use of a human consultant working with a template provided by a reporting consulting subsystem to produce a consultative report.

**Argument 7**

Appellant argues that Smith does not correct the deficiencies of Atlas/Bladen, with respect to disclosing the use of a human consultant working with a template provided by a reporting consulting subsystem to produce a consultative report.

**Examiner will address Appellant's arguments in sequence as they appear in the brief.**

**Argument 1**

In response to this argument, the Examiner respectfully submits that Appellant failed to address the long standing PTO principle and practice that a "claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101". Claim 1 recites "A system ... with an embedded consultation service ...". Furthermore, Appellant argues that "It is quite clear that consultants are associates of the laboratory and an integral component of the testing and reporting process".

The Specification describes the “embedded consultant” as a “consultant physician” in paragraph 0010 and that the embedded consultants time can be properly billed in paragraph 0048 of the published application.

### **Argument 2**

In response to this argument, the Examiner respectfully submits that the term “remarkable” is found 3 times in the body of the disclosure (paragraphs 0029, 0037 and 0042). In none of those instances is the term defined. These paragraphs disclose that the system allows clinicians to pursue reflexive testing “when such testing is indicated by prior abnormal or otherwise remarkable results”; and that the test results are compared to reference ranges to determine if the results are “abnormal”.

Appellant argues that the term “desirable” is also defined in the specification. The term “desirable” (or desirability) is not found in the body of the disclosure. Both "remarkable" and "desirable" as used in the present application are terms of relative degree. One of ordinary skill in the art would not know the metes and bounds of these claims.

### **Argument 3**

In response to this argument, the Examiner respectfully submits that Bladen in at least paragraph 0243 to 0245 discloses “templates within discipline specific master template module (106) are populated by a chief consultant” and that local consultants populates the templates for a

particular client. Additionally, Bladen discloses in at least paragraph 0244 and 0245 reference files for use by the consultant in completing the template.

#### **Argument 4**

In response to this argument, the Examiner respectfully submits that Atlas discloses:

- a template having a data source for generating a consultative report; (Atlas – Overview discloses that test results are communicated over the web. While Atlas does not disclose a consultant report, Bladen does as shown in the rejection for Claim 1.)
- reference ranges determined as a function of prior test results; (Atlas – Features – Efficient Order Entry discloses that new orders for existing patients automatically “default-in” patient information from the historical database.” Atlas – Features - A.R.N.O.L.D. tracks abnormal results and Lab OuterWare is patient centric, organizing ... results cumulative reporting and historical reference data by patient”);
- an alert subsystem; (Atlas - Overview - Figure discloses “sends notifications of results”);
- interpretive data comprising patient specific data (Atlas – Features – Results History Screen discloses a graph interpreting the historical data for a patient.

#### **Argument 5**

In response to this argument, the Examiner respectfully submits that Ross discloses a medical records system that insures proper billing for care rendered including consultations and which facilitates CPT coding.

**Argument 6**

In response to this argument, the Examiner respectfully submits that it appears as if the Appellant is attacking the references in a piecewise fashion, instead of in combination, as intended by the Examiner and as shown above in the rejections under 35 USC § 103(a).

**Argument 7**

In response to this argument, the Examiner respectfully submits that it appears as if the Appellant is attacking the references in a piecewise fashion, instead of in combination, as intended by the Examiner and as shown above in the rejections under 35 USC § 103(a).

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related appeals and interferences section of this Examiner's Answer.

**(12) Conclusion**

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/J. A. P./  
Examiner, Art Unit 3686  
Date: 3 March, 2010

/Gerald J. O'Connor/  
Supervisory Patent Examiner  
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